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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,324	03/12/2004	Peter J. Connolly	JJPR-0035	8354

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WOODCOCK WASHBURN LLP
ONE LIBERTY PLACE, 46TH FLOOR
1650 MARKET STREET
PHILADELPHIA, PA 19103

EXAMINER

DAVIS, BRIAN J

ART UNIT PAPER NUMBER

1621

DATE MAILED: 03/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/799,324

Applicant(s)

CONNOLLY ET AL.

Examiner

Brian J. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-235 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) See Continuation Sheet is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) See Continuation Sheet is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims allowed are 14-24,31-41,48-58,65,83,84,100-110,117-127,134-144,151-161,168-178,185-195 and 202-212.

Continuation of Disposition of Claims: Claims rejected are 25-30,42-47,59-64,66-82,85-99,111-116,128-133,145-150,162-167,179-184,196-201 and 213-235.

Continuation of Disposition of Claims: Claims objected to are
22,30,39,47,56,64,74,82,91,99,108,116,125,133,142,150,159,167,176,184,193,201,210,218,227 and 235.

DETAILED ACTION

Election/Restriction

Applicant's election of compound 108 (Table 6 page 73), with traverse, as the species elected to begin prosecution is acknowledged.

Applicant argues that a search and examination of all compounds encompassed by claim 66 would not present an undue burden upon the Office. While the examiner is in perfect agreement with applicant, the election/restriction encompassed all pending claims not simply claim 66.

The election/restriction was proper for reasons of record and is hereby made FINAL.

Information Disclosure Statement

The examiner notes for clarity of the record that there are cover sheets in the application for an IDS of record on 9/24/04, but not the IDS itself. The examiner respectfully requests that this IDS be included in applicant's next correspondence with the Office. The first IDS, the IDS of record on 5/21/04, is complete.

Claim Objections

Claims 22, 30, 39, 47, 56, 64, 74, 82, 91, 99, 108, 116, 125, 133, 142, 150, 159, 167, 176, 184, 193, 201, 210, 218, 227 and 235 are objected to because of the

following informalities: the claims contain a systematic typographical error. The word "ors" is extraneous and should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25, 42, 59, 77, 94, 111, 128, 145, 162, 179, 196, 213 and 230 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "...compound comprising a compound..." is unclear. That is, it is unclear how a compound can comprise anything other than itself. Claims 26-30, 43-47, 60-64, 78-82, 95-99, 112-116, 129-133, 146-150, 163-167, 180-184, 197-201, 214-218 and 231-235 are also rejected under 35 USC 112, second paragraph, as claims which depend from indefinite claims are also indefinite. *Ex parte Cordova*, 10 USPQ 2d 1949, 1952 (PTO Bd. App. 1989).

Claim 85 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The dependency of the claim is unclear. That is, the phrase "...in one of claims 83..." is unclear. Claims 86-93 are also rejected under 35 USC 112, second paragraph, as claims which depend from indefinite claims are also indefinite.

Claim 219 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

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regards as the invention. It is unclear how substituent R⁴ can be the natural side chain of Glycine (i.e. H) and the carbon to which is it attached in the diagram then have the stereochemistry indicated, because there would then no longer be a stereo center at that carbon. Claims 220-235 are also rejected under 35 USC 112, second paragraph, as claims which depend from indefinite claims are also indefinite.

Allowable Subject Matter

The elected species was searched and deemed free of the prior art. The search was therefore expanded as called for under current Office Markush practice, a compound-by-compound search. This resulted in the remaining species of claim 66 being searched. A rejection follows.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 66-82 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,750,369. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims teach a narrow subset of the set of compounds taught by instant claims 66-82.

With reference to the patented claims: Where a reference describes a sufficiently limited genus of a number of closely related compounds, the reference may be said to provide a description of those compounds just as if they were identified in the reference by name. *In re Schaumann*, 572 F2d 312, 197 USPQ 5 (CCPA 1978); *In re Petering*, 301 F2d 676, 133 USPQ 275 (CCPA 1962). That being the case, and following the well-established general principal in chemical cases that the disclosure of a species in a reference is sufficient to prevent a later applicant from obtaining a patent to a generic claim (*In re Steenbock*, 1936, CD 594, 473 OG 495), the generic claims of the instant application are per force obvious.

Allowable Subject Matter, continued

Since a double patenting rejection was the only rejection resulting from the search of all species of claim 66, the search was therefore again expanded, starting from the species of claim 14. This resulted in the determination that the subject matter of claims 14-65 and 83-218 is allowable. That is, taking into consideration the rejections outlined above, claims 14-24, 31-41, 48-58, 65, 83, 84, 100-110, 117-127, 134-144, 151-161, 168-178, 185-195 and 202-212 are allowed.

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The search was then expanded to include a single additional species from the Markush group described in claims 219-235. That species is defined when: $R^{1-3} = H$ and $R^4 =$ the side chain of the natural amino acid Glycine = H. A rejection for these remaining claims follows.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 219-235, in so far as they read on the species defined above, are rejected under 35 U.S.C. 102(b) as being clearly anticipated by JP 58150562 (CAPLUS abstract). The reference teaches applicant's compound: RN=88720-69-8.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Davis whose telephone number is 571-272-0638. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



BRIAN DAVIS
PRIMARY EXAMINER

Brian J. Davis
March 10, 2005